For more information:

This fact sheet summarizes key features of the Massachusetts Contingency Plan relating to risk characterization and evaluation. It is not a substitute for the regulations. Copies of the MCP may be purchased from

State Bookstore
Room 116
State House
Boston, MA 02133
(617) 727-2834

Western Office of
the Secretary of State
436 Dwight Street
Springfield, MA 01103
(413) 784-1376

This fact sheet is one of a series published by DEP concerning the MCP. To find out about other fact sheets please visit our website at http://www.mass.gov/dep/bwsc.

Or write to

MA DEP
Bureau of Waste Site Cleanup

1 Winter Street, 7th Floor
Boston, MA 02108

IF YOU WANT TO KNOW MORE ABOUT...	REFER TO MCP SUBPART
1. General Provisions of the MCP and Definitions	Subpart A: 40.0000
2. Roles and Responsibilities of the Various Parties	Subpart B: 40.0100
Best Response Action Management Approach (BRAMA)	40.0191
3. Notification Regulations, "Entering the System"	Subpart C: 40.0300
4. Preliminary Response Actions and Risk Reduction Measures	Subpart D: 40.0400
5. Tier Classification and Response Action Deadlines	Subpart E: 40.0500
6. Transition Provisions	Subpart F: 40.0600
7. Tier I Permits	Subpart G: 40.0700
8. Conducting Site Investigations and Implementing Remedial Response Actions	Subpart H: 40.0800
9. Risk Characterization and Evaluation Determining "How Clean is Clean Enough"	Subpart I: 40.0900
10. Response Action Outcomes and Activity and Use Limitations "Getting Out of the System"	Subpart J: 40.1000
11. Public Involvement and Technical Assistance	Subpart N: 40.1400
12. The Numerical Ranking System (NRS)	Subpart O: 40.1500
13. The Massachusetts Oil and Hazardous Material List	Subpart P: 40.1600

THE 1993 MASSACHUSETTS CONTINGENCY PLAN

RISK CHARACTERIZATION AND EVALUATION

How Clean Is Clean Enough?

Massachusetts Department of Environmental Protection
Robert W. Golledge, Jr., Commissioner

Bureau of Waste Site Cleanup
Deirdre C. Menoyo, Assistant Commissioner

July 1995; rev. May 2004

INTRODUCTION

The Commonwealth's Waste Site Cleanup Program has been redesigned to streamline and accelerate cleanup of releases of oil and hazardous material to the environment. Amendments to the Massachusetts Superfund Law (M.G.L. c. 21E) requiring the redesigned Program were enacted in July, 1992. In accordance with these amendments, the regulations for assessing and cleaning up releases of oil and hazardous material (the Massachusetts Contingency Plan or "MCP", which was originally promulgated in 1988) were substantially revised and became effective on October 1, 1993. In addition, a new Board of Registration has started to issue licenses for managing assessments and cleanups to experts meeting the licensing requirements. These "*Licensed Site Professionals*", or "LSPs", must be hired by those conducting response actions to make sure that the actions are performed in accordance with M.G.L. c.21E, the MCP and the Department's standards.

PURPOSE OF RISK CHARACTERIZATION

Chapter 21E establishes the standard for "***How Clean Is Clean Enough?***": response actions are complete when a condition of **"No Significant Risk"** of harm to health, safety, public welfare, or the environment exists or has been achieved at each site where a release has occurred. This standard requires consideration of both current and reasonably foreseeable uses of a site and its surrounding area. In addition, the statute requires that a cleanup reach levels of oil and hazardous material that would exist in the absence of the disposal site if feasible. This basic standard has not been changed in the recent amendments to the statute.

Risk Characterization is the process of describing and evaluating the risks posed by a site, and it is performed to determine whether or not further remediation is necessary. The 1993 MCP provides three options for defining a level of "no significant risk" or "how clean is clean enough": **Method 1** uses clear numeric standards for more than 100 common chemicals in soil and groundwater; **Method 2** allows for some adjustments in these standards to reflect site-specific conditions; and **Method 3** allows cleanup requirement goals to be defined on the basis of a site-specific risk assessment. With some limits, people conducting response actions can choose among these methods. <u>These methods are described in Subpart I of the new MCP (310 CMR 40.0900).</u>

Risk Characterization is also used to identify site conditions which would pose a significant risk of harm to health, safety, public welfare or the environment if those conditions were to exist *for even a short period of time*.

How Clean is Clean Enough? The Need for a Permanent Solution

Once the risks are evaluated, cleanup solutions which eliminate these risks can be developed and carried out. Cleanups must do two things:

Eliminate Significant Risk. The MCP defines a permanent cleanup solution as one which eliminates significant risks for any foreseeable period of time. If feasible, a permanent solution must be accomplished at all disposal sites. A temporary solution may be implemented when a permanent solution is not feasible, and it must eliminate significant risk for the current uses of the site and surrounding environment.

There are many ways to eliminate significant risk at disposal sites, and a particular remedial action may use one or more tools to accomplish this. The cleanup may actually reduce exposure point concentrations to acceptable levels by treating the contaminants. In other instances, the cleanup may eliminate or minimize exposure to the contaminants rather than reduce concentration levels. Restrictions on the use of the site is one means of controlling exposures to insure that no unacceptable risks occur. Such restrictions are called **<u>Activity and Use Limitations</u>**, and their use is described in Subpart J of the MCP.

Restore the Disposal Site to Background Levels. In addition to eliminating significant risk, a permanent solution, if feasible, must clean up the site to the levels which would exist in the absence of the disposal site. This is known as restoring the disposal site to **background levels**.

Risk to Public Welfare

The characterization of risk to public welfare considers factors such as the existence of nuisance conditions, loss of property value, and the loss of property use to determine whether the community in the vicinity of the disposal site has experienced significant adverse impacts to public welfare. This assessment also makes use of **Upper Concentration Limits**, which are chemical-specific concentrations (**Table 6**, 310 CMR 40.0996(4)) used to characterize potential future risks to public welfare which may result from leaving high levels of untreated contaminants in the soil or groundwater.

Risk to the Environment

The risk of harm to the wildlife and habitats at or near the disposal site must also be assessed. The environmental risk characterization looks first to establish whether or not there is the potential for environmental receptors to be exposed to the oil or hazardous material. If there is no potential for exposure, then the disposal site does not pose a significant risk to the environment. If the potential exists for environmental receptors to come into contact with the contaminants, then a more detailed environmental risk characterization is required. In addition, Upper Concentration Limits are used in the environmental risk characterization to evaluate the potential future risk to the environmental resources posed by high levels of untreated contaminants in soil and groundwater.

EVALUATING POTENTIAL IMMINENT HAZARDS

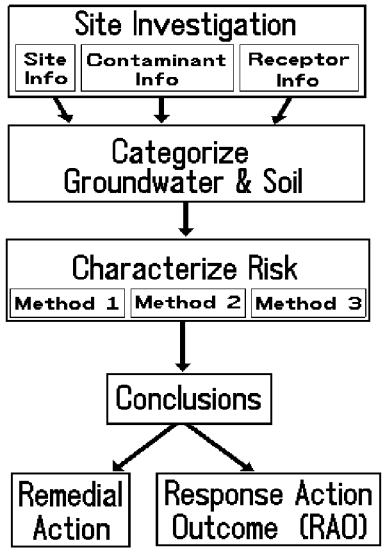
There are some site conditions which warrant immediate attention, including early notification to DEP and the implementation of an **Immediate Response Action** (IRA). Immediate Response Actions must be undertaken to address sudden releases of oil or hazardous material, **Imminent Hazards** and other time-critical conditions identified in the MCP.

When evaluating whether site conditions pose an Imminent Hazard, an assessment should identify potential receptors who are or are likely to be exposed to the contamination as a result of current activities at the site (e.g., residents using contaminated drinking water, children playing in contaminated surficial soil, and people breathing contaminated indoor air). Such an assessment is narrower in scope than most c.21E risk assessments (which also consider potential future exposures and conditions) in order to focus on actual or likely current exposures and to answer the question: *Should action be taken <u>now</u> to minimize or eliminate this exposure?* Quantitative Imminent Hazard Evaluations are not required at all c.21E sites: the decision to conduct such an evaluation depends upon many site-specific factors.

Such situations are considered to be **Imminent Hazards** under the MCP and **Immediate Response Actions** are required to address those conditions.

INFORMATION REQUIRED FOR RISK CHARACTERIZATION

An adequate site investigation is a prerequisite to risk characterization. When describing site risks and determining their significance, the following questions must be answered:



The validity of the conclusions reached concerning the need for further remediation directly depends upon the quality of the site investigation.

***<u>Who</u>* could be exposed to the contamination?** All of the people and the environment which may be affected by contaminants from the disposal site are considered when identifying the **human** and **environmental receptors**. The evaluation should focus on the people, biota and habitats most likely to be present and exposed at the site, taking into account not only the current use of the land, but also any expected future uses of the site and the surrounding area. Receptors can include children, adults, workers, animals, plants and wetlands.

***<u>Where</u>* are the receptors coming into contact with the contaminants?** The place where a receptor comes into contact with the oil or hazardous material is known as the **exposure point**. This is very important because the concentrations of oil or hazardous materials - and the risks resulting from exposure to these concentrations - are measured and evaluated at the exposure points, even if the exposure points are not at the disposal site itself. If the receptor is not physically at the disposal site, there must be a **migration pathway** or a way for the oil or hazardous material to travel to the receptor. Common migration pathways include groundwater and air.

What **types of oil or hazardous materials are present and in what amounts?** A systematic assessment of site conditions examines the amount and types of oil or hazardous materials present at the disposal site. Air, soil, and ground or surface water are the **environmental media** most often examined. Contaminants may be present in one or more media. The concentration of a contaminant at the location where a receptor may contact the material is the **exposure point concentration**.

How **could the contaminants get to people or the environment?** Contaminants can enter a human body, animal or plant in a variety of ways. The particular way in which a contaminant enters the organism is called the **route of exposure**. Common examples of routes of exposure include **drinking** contaminated groundwater, **absorbing** contaminants through the skin, and **breathing** them in the air.

Ultimately, the risk that a disposal site presents depends on the types, quantities and concentrations of the oil or hazardous materials (some materials are more hazardous than others), the length of time someone may be exposed to the contaminant, the route of exposure, and the sensitivity of the receptors (e.g., the elderly, pregnant women and children are often more sensitive to certain contaminants than other receptors).

The MCP establishes **Soil and Groundwater Categories** based upon the potential exposures which may result from the presence of oil or hazardous material in these commonly contaminated media. Once the soil and groundwater at a site has been categorized, applicable standards can be identified.

The three soil categories span a range from *high exposure potential:* **Category S-1 soil** (e.g. surficial soil in residential neighborhoods) to *low exposure potential:* **Category S-3 Soil** (e.g. buried soil in a lightly used industrial area). The soil category is determined by four site-specific factors: accessibility of the soil, nature of receptors present, frequency of use of the site and the intensity of the use of the site. Because the three soil categories describe a range of potential exposures these categories are mutually exclusive: soil is *either* S-1, S-2 *or* S-3.

The three groundwater categories describe different exposures which may result from contaminated groundwater. **Category GW-1 Groundwater** is a resource protected for its current or potential future use as drinking water. **Category GW-2 Groundwater** may act as a source of volatile material to indoor air. **Category GW-3 Groundwater** may discharge oil or hazardous material to surface water. As these categories describe *different* potential exposures, the groundwater categories are *not* mutually exclusive: ***all*** groundwater is assumed to eventually discharge to surface water and thus all groundwater is by definition GW-3. Groundwater may also be GW-1 and/or GW-2 depending upon site-specific factors.

Method 3: Site-Specific Risk Assessment

Using Method 3 to characterize risk allows decisions about the need for remediation and the appropriate level of cleanup required to be made on a case-by-case basis. The risks of harm to health, public welfare and the environment are evaluated independently by site.

Risk of Harm to Human Health

The risk of harm is evaluated by comparing current or expected exposure point concentrations to existing standards *and* by evaluating all current and foreseeable site-related exposures and comparing calculated cancer and non-cancer risks to risk limits promulgated in the MCP. (Note that Method 1 standards are not applicable under Method 3 as Method 1 is an ***alternative*** to Method 3.)

Potential negative health effects are divided into two categories: those which present an increased risk of developing cancer from exposure to any amount of a potential cancer-causing substance; and non-cancerous health effects (such as damage to the nervous system, liver or other organs) caused by intake of more than a threshold amount of a contaminant. A **threshold amount** is the level at which adverse health effects may be expected to occur.

The **Cumulative Receptor Cancer Risk** is an estimate of how much a person's lifetime cancer risk is increased as a result of exposure to the contaminants, that is, the excess risk due to the contaminants from the site. The calculated Cumulative Receptor Cancer Risk is compared to a cumulative cancer risk limit of one-in-one hundred thousand (1 in 100,000). That means that an individual's exposure cannot increase his lifetime cancer risk by more than 1 in 100,000. Anything above this is considered to be a significant risk and any cleanup solution must reduce the excess risks below this level. This limit is very strict, especially since in the U.S. today the risk of an individual developing cancer is 1 in 4.

The limit for **Cumulative Receptor Non-cancer Risk** (or threshold risk) is also very protective. Exposure to contaminants which affect the same organ system or which share the same mechanism of toxicological action is totalled and measured against safe levels of these chemicals to calculate what is known as the **Hazard Index**. Total daily exposure to the contaminants cannot exceed the cumulative non-cancer risk limit which is a hazard index equal to one.

Examples of such Method 2 demonstrations include:

- **!** The use of site-specific leaching models to document that residual soil levels will not result in an exceedance of an applicable groundwater standard;
- **!** The use of site-specific volatilization models to document that groundwater contaminants will not result in unacceptable indoor air concentrations;
- **!** The use of site-specific migration models to demonstrate that the groundwater will not pose a significant risk when it discharges to surface water.

Method 2 may also be used to "*fill in*" missing Method 1 standards. If DEP has not yet published a standard for a chemical of interest at a disposal site then the equations described in the regulations may be used to identify a standard for that chemical in a manner identical to the way DEP developed the original Method 1 standards. Such a Method 2 standard would be used in the risk characterization process as if it had been developed by DEP.

Note that there are some Method 1 standards which cannot be modified under Method 2. For example, groundwater protected as a current or potential source of drinking water must meet the promulgated GW-1 standards listed in Table 1. Similarly, while some site-specific information may be used to adjust the leaching-component of the soil standards, the results cannot exceed soil standards based upon direct contact exposures. These soil standards are listed in **Table 5** (310 CMR 40.0985(6)).

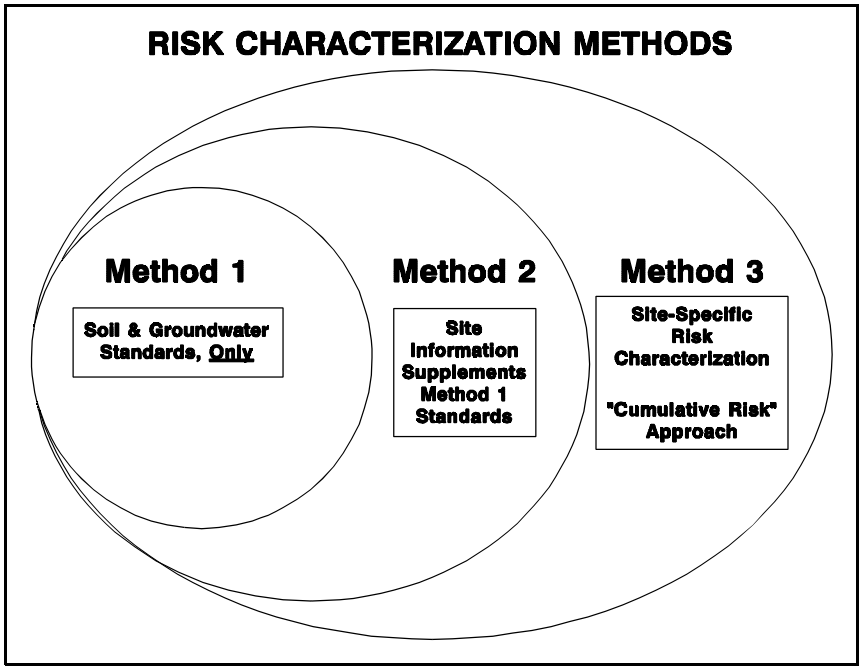
The Risk Characterization process under Method 2 is similar to that described for Method 1: the comparison of site conditions to the applicable soil and groundwater standards as promulgated or as modified to reflect site-specific fate and transport information. If the concentration of an oil or hazardous material is *greater* than these levels, then some form of remedial action is necessary. If, however, the concentrations reported at a site are *lower* than the identified standards, then a level of No Significant Risk exists, and no further remedial action is required unless it is feasible to reduce the levels of contaminants closer to background.

EVALUATING RISKS FROM A DISPOSAL SITE

Once the nature and extent of the contamination is determined, all potential receptors identified and the soil and groundwater categorized, the risks are evaluated to answer the questions:

1. *How serious is the risk?*
2. *Is a remedial action required?*
3. *To what extent must the disposal site be cleaned up?*

Three different methods of risk characterization are described in the Contingency Plan so that the complexity of the assessment can match the complexity of the disposal site. It is important to note that each method offers the same high level of protection to public health and that, with some limitations, *any* method may be used at a disposal site to demonstrate that the site poses no significant risk of harm to health, safety, public welfare and the environment.



Method 3 may be used to characterize risk at *any* disposal site, while Methods 1 & 2 are an option at most sites, with some limitations. *Please check the regulations...*

Risk to Safety

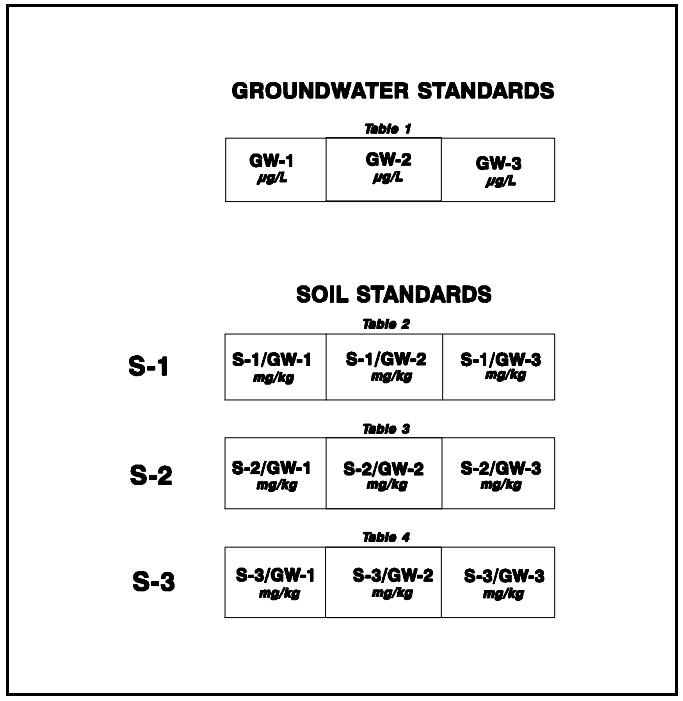
Regardless of which of the three risk characterization methods is used, the risk to safety is characterized the same way. Site conditions are evaluated to see whether they pose, or will in the future pose, a threat of physical harm or bodily injury to people. Examples of potential safety risks include the presence of corroded drums containing oil or hazardous material, or the presence of explosive vapors.

Method 1 - Using Promulgated Standards In Soil And Groundwater

The MCP contains lists of soil and groundwater standards developed in a health-protective (conservative) manner and corresponding to the groundwater and soil categories described previously. Once the groundwater and soil categories have been identified for a disposal site, the applicable standards can be read directly from the tables of Subpart I.

The standards for groundwater categories GW-1, GW-2 and GW-3 are listed in **Table 1** (310 CMR 40.0974(2)): when more than one groundwater category applies to a site all the applicable standards must be considered. The soil standards were developed considering both the risks associated with direct contact with the contaminated soil and the potential for the contaminants to leave the soil and contaminate the underlying groundwater. Thus, identifying the applicable soil standards depends upon both the category of soil and the category of groundwater: **Table 2** (310 CMR 40.0975(6)(a)) lists the standards for category S-1 soils overlying GW-1, GW-2 and/or GW-3 groundwater. **Tables 3** and **4** contain the applicable standards for soil categories S-2 and S-3, respectively.

The actual Risk Characterization under Method 1 is simply the comparison of site conditions to the applicable soil and groundwater standards. If the concentration of an oil or hazardous material is *greater* than an applicable soil or groundwater standard then some form of remedial action is necessary. If, however, the concentrations reported at a site are *lower* than the applicable soil or groundwater standards, then a level of No Significant Risk exists, and no further remedial action is required unless it is feasible to reduce the levels of contaminants closer to background.



Schematic of the MCP tables listing the numerical Method 1 standards.

Method 2 - Using Site-Specific Information To Complement The Method 1 Standards

In developing the Method 1 soil and groundwater standards, DEP made many health-protective assumptions about potential exposures and the movement of contaminants to ensure that the standards represent a level of No Significant Risk at virtually all disposal sites to which they are applicable. For any given disposal site, however, investigations may reveal that the **fate and transport models** employed to develop the Method 1 standards overestimate potential risks. Under Method 2, site-specific information may be used to demonstrate and document that a concentration of oil or hazardous material which exceeds an applicable Method 1 standard poses No Significant Risk.